REMARKS/ARGUMENTS

Claims 13-16, 18-22, 26-27, 29-31, 36-42, and 47-52 remain in this application. Applicants have amended, without prejudice, claims 26, 27, and 31 and have cancelled, without prejudice, claims 25, 34, and 43-46. Applicants reserve the right to prosecute such cancelled subject matter from such amended and cancelled claims in subsequent continuation/divisional applications. Support for the amendments to claims 26 and 31 can be found in cancelled claim 26 and support for new claims 47-52 can be found throughout the specification, including page 10, line 5. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Rejections Under 35 USC 103

Claims 13-16, 18-22, 25-27, 29-31, 34, and 36-46 were rejected under 35 USC 103(a) as being unpatentable over the combined disclosures of Shah et al US Patent No. 6,126,969 (the '969 Patent) in view of Sakamoto et al US Patent No. 4,828,840 (the '840 Patent). See Pages 2-5 of the Office Action. Applicants respectfully disagree.

With respect to the '969 Patent, the Office Action acknowledges that "the reference is silent to the ratio of the water insoluble polymer relative to the enteric polymers in the instant claims." See page 3 of the Office Action. However, as noted by Applicants in the previous responses, '969 Patent does not disclose a particle containing any enteric polymer. Rather, the'969 Patent actually teaches away from the use of such polymers. For example, the '969 Patent states that it desires a "predictable rate which is independent of inter-and intra-subject physiological variations such as pH. . . . The resulting combined immediate-release/sustained-release formulation provides higher reproducibility of drug release rates than other sustained-release dosage forms utilizing conventional enteric sustained-release coating compositions . . . ." See, e.g., col. 5, lines 45-60 of the '969 Patent.
While the '840 Patent does disclose a particle have a coating comprised of a controlled release composition comprising one or more enteric polymers and one or more insoluble film forming polymers, Applicants assert that as the '969 Patent teaches away from the use of particles containing enteric polymers, one of ordinary skill in the art would not look to

combine the teachings of the '969 Patent with the '840 Patent (which includes enteric polymers).

Further, even if one of ordinary skill in the art would have considered combining the references (which Applicants respectfully disagree as stated above), the '969 Patent fails to disclose, or suggest, a liquid suspension in which such two types of particles are suspended and the '840 Patent fails to any liquid suspension dosage form containing such particles.

Further, as discussed above, in the interests of furthering this application to allowance, Applicants have amended the current claims (without prejudice) to recite both that the particles contain an NSAID and the pKa of the NSAID is greater than the pH of the liquid suspension pharmaceutical dosage form. The '840 Patent fails to disclose, or suggest, particles containing NSAIDs, such as ibuprofen. With respect to the pH limitation, the Office Action asserts on page 4 that:

> "Regarding the pKa of the at least one active agent contained in the sustained release particles and its relation to the pH of the suspension it is the position of the Examiner that the prior art inherently meets this limitation. It is the position of the Examiner that the pKa is a function of the stricture of the instant invention, and is due to the arrangement of the immediate and sustained release particles. Since the prior art discloses the same arrangement of particles and components, the prior art must also possess the same pKa and pH limitations as the instant claims."

Applicants again respectfully disagree. While the pKa of at least one active ingredient contained in said second portion of particles is an inherent feature of that ingredient, the choice of the active ingredient and the pH of the suspension are not inherent, but rather are under the control of the formulator. For example, the pKa for ibuprofen (as recited in new claims 47-52) is 4.4. The Office Action fails to address why one of ordinary skill in the art, in reading the '969 Patent and the '840 Patent, would have been suggested to maintain the pH of a liquid suspension dosage form containing particles containing ibuprofen to less than 4.4. Applicants have found that maintaining the pH of the liquid suspension pharmaceutical dosage form lower than the pKa of the active agent inhibits the NSAID from being solubilized in the suspension, which would otherwise compromise the sustained release property of the coated particles. Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5015/WEM.

Respectfully submitted,

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